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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,905	04/30/2007	Kunihiro Hattori	14875-161US1 C1-A0313P2-U	2076

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,905	HATTORI ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *20-22 and 29-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19 and 23-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 – 38 are pending.

2. Claims 20 – 22 and 29 – 38 are improper because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n) and 37 CFR § 1.75(c).

Claims 20 – 22 and 36 – 38 improper under 37 CFR § 1.75(c) because each of these claims refers back to more than one feature or embodiment in the base claims.

Claims 21 and 37 are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore claims 20 – 22 and 29 – 38 have been withdrawn from consideration. If these claims are amended to comply with 37 CFR § 1.75(c) and to recite statutory subject matter, the amended claims may be rejoined with the appropriate invention Group as set forth below, withdrawn form consideration as drawn to non-elected inventions, or subject to an additional restriction requirement, as appropriate.

Claims 1 – 19 and 23 – 28 are presently under consideration.

Restriction Requirement

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 7 and 8, and to compositions comprising said antibody.

II. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 9 and 10, and to compositions comprising said antibody.

III. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 19 and 20, and to compositions comprising said antibody.

IV. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 13 and 14, and to compositions comprising said antibody.

V. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 23 and 24, and to compositions comprising said antibody.

VI. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 5 and 6, and to compositions comprising said antibody.

VII. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 17 and 18, and to compositions comprising said antibody.

VIII. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 15 and 16, and to compositions comprising said antibody.

IX. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 21 and 22, and to compositions comprising said antibody.

X. Claims 1 – 19, drawn to a bispecific antibody that substitutes for the effect of a functional protein, in particular comprising an anti-AR2 chain comprising SEQ ID NOS: 11 and 12, and to compositions comprising said antibody.

XI. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:50.

XII. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:54.

XIII. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:58.

XIV. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:62.

XV. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:66.

XVI. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:70.

XVII. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:74.

XVIII. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:78.

XIX. Claims 23 – 28, drawn to a bispecific antibody that recognizes both an enzyme and a substrate thereof, in particular comprising SEQ ID NO:82.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. The inventions listed as Groups I – X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I – X are deemed to have no special technical feature that defines the contribution over the prior art of Ledbetter et al. (US Patent No. 6,010,902; see entire document). Ledbetter et al. teach bispecific antibodies which bind to CD3 and other T cell receptors and induce proliferation of T cells (e.g. Example 6), i.e. substitute for the effect of the antigen. Therefore, the teachings of Ledbetter et al.

anticipate at least the instant claim 1, and thus inventions of Groups I – X do not have a special technical feature when viewed over the teachings of Ledbetter et al.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and so lack unity of invention.

The inventions of Groups XI – XIX are deemed to have no special technical feature that defines the contribution over the prior art of Yamazaki et al. (US Patent No. 5,496,549; see entire document). Yamazaki et al. teach a bispecific antibody recognizing both a protease and a platelet (e.g. claim 1). One of skill in the art is aware that a platelet comprises multiple proteins, i.e. substrates for proteases. Since the antibody of Yamazaki et al. is structurally the same as the antibody recited in the instant claim 23, it inherently has the same functional properties. Therefore, the teachings of Yamazaki et al. anticipate at least the instant claim 23, and thus inventions of Groups XI – XIX do not have a special technical feature when viewed over the teachings of Yamazaki et al.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and so lack unity of invention.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If any one of Groups I – X is elected, applicant is required to elect a species wherein the anti-AR1 chain comprises:

A. SEQ ID NOS: 1 and 2; or
B. SEQ ID NOS: 3 and 4.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, for the same reasons as set forth in section 4 supra.

If any one of Groups XI – XIX is elected, applicant is required to elect a species wherein the antibody also comprises:

A. SEQ ID NO:43; or
B. SEQ ID NO:46.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, for the same reasons as set forth in section 4 supra.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/
ILIA OUSPENSKI, Ph.D.
Primary Examiner
Art Unit 1644

June 18, 2009